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| 09/766,863      | 01/19/2001  | Thomas J. Powell     | 15966-641 CURA-141) | 9092             |

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/24/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/766,863

Applicant(s)

POWELL ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6,7,10-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,10-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' response to the office action and amendment (Paper No. 12) filed on January 13, 2003 has been entered.
2. Claims 4, 5, 8, 9 and 16 are cancelled and the claims 1-3, 6-7, 10-15, 17-20 are pending.

***Response to Arguments***

3. Applicant's response to the office action (Paper No.12) is fully considered and deemed persuasive in part.
4. With reference to the rejection in the previous office action under 35 U.S.C. 102(a), applicants' arguments and amendment have been fully considered and the rejection is moot in view of the amendment and new grounds of rejection.
5. With reference to the rejection in the previous office action under 35 U.S.C. 103(a), applicants' arguments and amendment have been fully considered and the rejection is moot in view of the amendment and new grounds of rejection. Applicants' particular argument that Johnson et al. does not teach at least three mammalian cell types selected from the recited list, is not persuasive because Johnson et al. teach plurality of cell lines that include three and plurality of cell types comprise hepatoma cells (HepG2), B-cells, T-cells, astrocytes (see page 27, lines 1-11, page 30, lines 8-10, page 20, table, page 27, lines 1-11). Hence, although Johnson did not teach the limitation "at least three cell types", it is obvious that plurality of cell types include three cell types and the specific cell types listed in the instant amended claims would be obvious over a combination of teachings.

**New Grounds of Rejection necessitated by the Amendment**

***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-7, 10-15, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 99/37817) and in view of Kamb et al. (USPN. 5,998,136).

Johnson et al. teach a method of identifying the function of a test compound, wherein Johnson et al. disclose that the method comprises (i) providing a plurality of cells, the plurality comprising at least two different cell types and exposing the plurality of cells with a test compound (see page 53, lines 1-60; (ii) measuring expression of one or more genes in the said cell types and comparing the expression of said genes with a reference cell and an alteration in said gene expression indicates the function of said test compounds (see page 53, claim 1, lines 7-15, page 11, lines 3-5). Johnson et al. also teach that the method comprises (i) expression of at least two genes in two different cell types (see page 53, claims 2 and 3) (ii) defines different gene-cell combination as the same gene in two or more host cell types or, two or more different

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genes in the same host cell type (see page 7, lines 24-31), which indicates more than two cell types and more than two genes are permissive in the said method which is supported by the results in table 1 of Johnson et al. disclosure (see page 20, table 1, lines 1-4); cells are provided in container (plates) and the cell types consist of HepG2 cells, B-cells, T-cells astrocytes (see page 27, lines 1-11, page 30, lines 8-10); gene expression greater than or equal to 3-fold was taken as an indication of modulated gene expression by a test compound. (see page 28, lines 19-20); test compound could be a polypeptide (see page 54, claim 14); plurality of cell types were contacted with two or more test compounds (see page 54, claim 12); plurality of cells include mammalian cells from human subjects (see page 39, lines 12-19). Although Johnson et al. teach HepG2 cell type, Johnson et al. did not specifically other mammalian cell types listed in the instant claims, that is cell types comprising osteosarcoma, erythroleukemia, monocytic, endothelial, fibroblast, NK-cell, normal osteoblast, normal lung fibroblast.

Kamb teaches a method for identifying test compounds wherein Kamb teaches that the method comprises identifying the function (inhibitory effect) of a test compound on cells and measuring gene expression (see column 34, lines 41-67); the cell types comprise most preferably mammalian cells (see column 35, lines 1-7); Cell types comprise, fibroblast, endothelial, epithelial cell types (see columns 13-14, table 1). Kamb also teach detection of differential expression using sequence tags and polymerase chain reaction (see column 21, lines 41-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of drug target screening as taught by Johnson et al. with the method of Kamb which is applicable to select different mammalian cell types because Kamb states that mammalian host cells are more preferable and the compounds identified by

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screening could be used to prevent diseases such as cancer, neurodegenerative, immunological or inflammatory diseases” (see column 35, lines 1-7, column 43, lines 39-57). An ordinary practitioner would have been motivated to combine the method of Johnson et al. with the method of Kamb in order to achieve the expected advantage of developing a sensitive and diagnostic method for screening a test compound because by incorporating specific mammalian cell types one could target specific human diseases.

### ***Conclusion***

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
March 20, 2003



JEFFREY FREDMAN  
PRIMARY EXAMINER